

BARNES & THORNBURG



11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313
(317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: Unknown

Confirmation No.: Unknown

Application No.: 10/658,667

Invention: **Neurotherapeutic Composition and Method**

Applicant: Gary A. Koppel

Filed: September 9, 2003

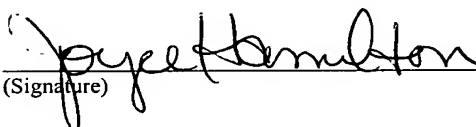
Attorney Docket: 22064-69748

Examiner: Unknown

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on October 3, 2003


(Signature)

Joyce Hamilton
(Printed Name)

INFORMATION DISCLOSURE STATEMENT FILED UNDER 37 C.F.R. § 1.97(b)(3)

Commissioner for Patents
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Sir:

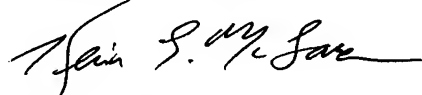
This statement is filed in the application identified above pursuant to 37 C.F.R. § 1.56. In accordance with 37 C.F.R. § 1.98(d), copies of the references are not required since copies of the listed references were included in an Information Disclosure Statement compliant with 37 C.F.R. § 1.98(a)-(c), and filed during the prosecution of parent U.S. Application Serial No. 09/640,363 filed August 16, 2000 now Patent No. 6,627,625 to be issued on September 30, 2003, which is relied upon for an earlier effective filing date under 35 U.S.C. § 120. No representation is intended that a complete search has been made of the prior art or that no better art references than those listed herein are available. The filing of this Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in § 1.56(b). None of the cited art is believed to disclose or

suggest the invention recited in the claims of the above-identified application. It is therefore believed that the claimed invention is patentably distinguishable over these references.

Please charge any fees that might be due in connection with this Information Disclosure Statement to our Deposit Account No. 10-0435, with reference to our Matter No. 22064-69748. An extra copy of this Information Disclosure Statement is enclosed for that purpose.

Respectfully submitted,

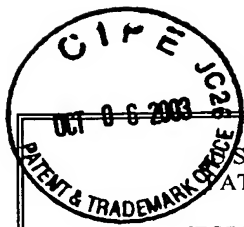
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A handwritten signature in black ink, appearing to read "Kevin L. McLaren".

Kevin L. McLaren

Agent Reg. No. 48,531

KLM:jdh
Indianapolis, IN
(317) 231-7776

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
22064-69748SERIAL NO.
10/658,667APPLICANT
Gary A. KoppelFILING DATE
September 9, 2003GROUP
Unknown

U.S. PATENT DOCUMENTS

| *Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
|-------------------|----|-----------------|---------------|------------------|-------|----------|----------------------------|
| | AA | 4,268,503 | May 19, 1981 | Imanaka et al. | | | |
| | AB | 4,302,447 | Nov. 24, 1981 | Horrobin | | | |
| | AC | 4,594,247 | Jun. 10, 1986 | Brier | | | |
| | AD | 5,763,603 | Jun. 9, 1998 | Trickes | | | |
| | AE | 5,795,877 | Aug. 18, 1998 | Jackson et al. | | | |
| | AF | 5,824,662 | Oct. 20, 1998 | Slusher et al. | | | |
| | AG | 5,863,536 | Jan. 26, 1999 | Jackson et al. | | | |
| | AH | 5,880,112 | Mar. 9, 1999 | Jackson et al. | | | |
| | AI | 5,905,076 | May 18, 1999 | Singh et al. | | | |
| | AJ | 5,912,242 | Jun. 15, 1999 | Pevarello et al. | | | |
| | AK | 5,968,915 | Oct. 19, 1999 | Jackson, et al. | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation Yes No |
|--|----|-----------------|---------------|---------------|-------|----------|-----------------------|
| | AL | WO 95/20980 | Aug. 10, 1995 | PCT | | | |
| | AM | WO 97/10247 | Mar. 20, 1997 | PCT | | | |
| | AN | 1 508 977 | Apr. 26, 1978 | Great Britain | | | |
| | AO | WO 97/35839 | Oct. 2, 1997 | PCT | | | |
| | AP | WO 98/32766 | Jul. 30, 1998 | PCT | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|----|--|
| AR | K.C. Montgomery, "The Relation Between Fear Induced by Novel Stimulation and Exploratory Behavior," <i>J. Comp. Physiol. Psychol.</i> , vol. 48, 254-60 (1955). |
| AS | H.V. Duijn, P.A. Schwartzkroin, and D.A. Prince, "Action of Penicillin on Inhibitory Processes in the Cat's Cortex," <i>Brain Res.</i> , vol. 53, 470-476 (1973). |
| AT | H. Meyer and D. Prince, "Convulsant Actions of Penicillin: Effects on Inhibitory Mechanisms," <i>Brain Res.</i> , vol. 53, 477-482 (1973). |
| AU | B. Hochner, M.E. Spira, and R. Werman, "Penicillin Decreases Chloride Conductance in Crustacean Muscle: A Model for the Epileptic Neuron," <i>Brain Res.</i> , vol. 107, 85-103 (1976). |
| AV | A.B. Chernomordik, "Methods of Therapeutic Application of Massive Doses of Penicillin," <i>Klin. Med.</i> , vol. 2, 102-105 (1980). |
| AW | Pickles et al., "Antagonism by Penicillin of Gamma-Aminobutyric Acid Depolarizations at Presynaptic Sites in Rat Olfactory Cortex and Cuneate Nucleus <i>In Vitro</i> ," <i>Neuropharmacology</i> , vol. 19, 35-38 (1980). |
| AX | D.J. Sanger, "GABA and the Behavioral Effects of Anxiolytic Drugs," <i>Life Sciences</i> , vol. 36, 1503-1513 (1985). |
| AY | P. Chow and D. Mathers, "Convulsant Doses of Penicillin Shorten the Lifetime of GABA-Induced Channels in Cultured Central Neurones," <i>Br. J. Pharmac.</i> , vol. 88, 541-547 (1986). |
| AZ | Z.I. Bashir and O. Holmes, "N-methyl-D-aspartate Receptors and the Enhancement of Somatosensory Evoked Potentials in Penicillin Epileptogenesis in Rats," <i>Physiological Society</i> , 19P (1987). |

Examiner

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 22064-69748 | SERIAL NO. 10/658,667 |
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U.S. PATENT DOCUMENTS

| *Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
|-------------------|----|-----------------|---------------|-------------------|-------|----------|----------------------------|
| | BA | 5,977,090 | Nov. 2, 1999 | Slusher et al. | | | |
| | BB | 6,004,946 | Dec. 21, 1999 | Slusher et al. | | | |
| | BC | 6,015,809 | Jan. 18, 2000 | Zhu et al. | | | |
| | BD | 6,017,903 | Jan. 25, 2000 | Slusher et al. | | | |
| | BE | 6,204,260 B1 | Mar. 20, 2001 | Bruns, Jr. et al. | | | |
| | BF | 2002/0002159 A1 | Jan. 3, 2002 | Koppel | | | |
| | BG | 2002/0028761 A1 | Mar. 7, 2002 | Koppel et al. | | | |
| | BH | 2002/0049187 A1 | Apr. 25, 2002 | Bruns, Jr. et al. | | | |
| | BI | | | | | | |
| | BJ | | | | | | |
| | BK | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation Yes No |
|--|----|-----------------|---------------|---------|-------|----------|-----------------------|
| | BL | WO 99/36403 | July 22, 1999 | PCT | | | |
| | BM | WO 00/62067 | Oct. 19, 2000 | PCT | | | |
| | BN | | | | | | |
| | BO | | | | | | |
| | BP | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|--|
| | BR | V. Serval et al., "Competitive Inhibition of N-Acetylated-alpha-Linked Acidic Dipeptidase Activity by N-Acetyl-L-Aspartyl-beta-Linked L-Glutamate," <i>J. Neurochemistry</i> , vol. 55, 39-46 (1990). |
| | BS | E. Horn, K. Esseling, and R. Wagner, "Time Course of Interictal EEG Patterns Induced by a Penicillin Injection into the Olfactory Cortex," <i>Pharmacology Biochemistry & Behavior</i> , vol. 40, 351-357 (1991). |
| | BT | A.L. Horne et al., "The Pharmacology of Recombinant GABA _A Receptors Containing Bovine α_1 , β_1 , γ_2 Subunits Stably Transfected into Mouse Fibroblast L-cells," <i>Br. J. Pharmacology</i> , vol. 107, 732-737 (1992). |
| | BU | I.V. Batueva, N.P. Veszelkin, and R. Veskov, "Effect of Penicillin on Synaptic Activity of Isolated Spinal Cord Motoneurons of Lamprey," <i>Neirofiziologiya</i> , vol. 24 (2), 151-160 (1992). |
| | BV | O. Orwar et al., "Increased Intra- and Extracellular Concentrations of γ -Glutamylglutamate and Related Dipeptides in the Ischemic Rat Striatum: Involvement of γ -Glutamyl Transpeptidase," <i>J. Neurochemistry</i> , vol. 63, 1371-1376 (1994). |
| | BW | V. Varga et al., "Endogenous γ -L-Glutamyl and β -L-Aspartyl Peptides and Excitatory Aminoacidergic Neurotransmission in the Brain," <i>Neuropeptides</i> , vol. 27, 19-26 (1994). |
| | BX | A.V. Kalueff, G.E. Samonina, and I.P. Ashmarin, "Penicillins and Their Derivatives: Antiulcer/Antistress Properties?" <i>Neuropsychopharmacology</i> , vol. 10 (35), 272S (1994). |
| | BY | A.V. Kaluev, G.E. Samonina, and I.P. Ashmarin, "Behavioral Effects of Penicillin in a Test for Anxiety in Rats," <i>Bulletin of Experimental Biology and Medicine</i> , vol. 120 (10), 984-986 (1995). |
| | BZ | P.F. Jackson et al., "Design, Synthesis, and Biological Activity of a Potent Inhibitor of the Neuropeptidase N-Acetylated α -Linked Acidic Dipeptidase," <i>J. Med. Chem.</i> , vol. 39(2), 619-622 (1996). |

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| Examiner | Date Considered |
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U.S. PATENT DOCUMENTS

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|-------------------|----|-----------------|------|------|-------|----------|----------------------------|
| | CA | | | | | | |
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FOREIGN PATENT DOCUMENTS

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| | CL | | | | | | |
| | CM | | | | | | |
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| | CO | | | | | | |
| | CP | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|----|---|
| CR | A. Ungerer et al., "γ-L-Glutamyl-L-Aspartate Induces Specific Deficits in Long-Term Memory and Inhibits [³ H]Glutamate Binding on Hippocampal Membranes," <i>Brain Res.</i> , vol. 446, 205-211 (1988). |
| CS | Drummond, J. et al., "Synthesis of a Cognition Enhancing Beta-Lactam Fused Gamma-Lactam", <i>Tetrahedron Lett.</i> , 28(44):5245-8 (1987). |
| CT | Kabanov, A. et al., "The neuroleptic activity of haloperidol increases after its solubilization in surfactant micelles," <i>FEBS Letters</i> 07908, 258(2):343-5 (1989). |
| CU | Nilsson, B. et al., "β-Lactam Analogues of Oxotremorine 3- and 4-Methyl-Substituted 2-Azetidinones," <i>J. Med. Chem.</i> , 33:580-84 (1990). |
| CV | E.F. Reynolds, "Martindale, The Extra Pharmacopoeia Clavulanic Acid," <i>Royal Pharmaceutical Society, London</i> , 211 (1996) XP-002161510. |
| CW | Passani et al., "N-acetylaspartylglutamate, N-acetylaspartate, and N-acetylated α-linked acidic dipeptidase in human brain and their alterations in Huntington and Alzheimer diseases," <i>Molec. and Chem. Neuropathology</i> , vol. 31, No. 2, 97-118 (1997). |
| CX | Macknin, M.L., "Behavioral changes after amoxicillin-clavulanate," letter, <i>Pediatric Infectious Disease Journal</i> , Vol. 6, No. 9, 873-74 (1987) XP-000987254. |
| CY | Tsai, Guochuan et al., "Abnormal Excitatory Neurotransmitter Metabolism in Schizophrenic Brains," <i>Archives of General Psychiatry</i> , Vol. 52, No. 10, pages 829-636 (1995) XP-00987256. |
| CZ | Pangalos et al., "Isolation and expression of novel human glutamate carboxypeptidases with N-acetylated α-linked acidic dipeptidase and dipeptidyl peptidase IV activity", <i>J. Bio. Chem.</i> , Vol. 274(13):8470-83 (1999). |

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| Examiner | Date Considered |
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|-------------------|----|-----------------|------|------|-------|----------|----------------------------|
| | DA | | | | | | |
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FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation Yes No |
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| | DP | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|--|
| | DR | Kalueff, A.V., "Positive effects of penicillin-related drugs in stress and anxiety," Derwent Drug File Abstracts Online (STN-DRUGU), abstract no. 1996-33680 (1995). |
| | DS | Iwamoto et al., "N-(2-Azetidinone-4-carbonyl)histidine derivative," English abstract from Japanese Patent JP360193982A from JPO database (1985). |
| | DT | |
| | DU | |
| | DV | |
| | DW | |
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